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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 554,267	07 24 2000	ANUSCHIRWAN PEYMAN	02481.1669	2235

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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 01 02 2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,267

Applicant(s)

PERMANENT

Examiner

Jane Dara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 CFR 1.136(a) and (b). Even though an extension may be available, it must be requested after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory period must be filed by the last day of the period.
- If NO period for reply is specified above, the maximum statutory period will apply and will be SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED under 37 CFR 1.131.
- Any reply received by the Office later than three months after the mailing date of this communication, even if it does not have a timely earned patent term adjustment, See 37 CFR 1.134(c).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is **FINAL** 2b) ☐ This action is non-final
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is a) ☐ approved b) ☐ disapproved by the Examiner
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f)
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) to a provisional application
- a) ☐ The translation of the foreign language provisional application has been received
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449, Paper No. 14)
- 4) ☐ Notice of Informal Patent Application (PTO-900)
- 5) ☐ Notice of Informal Patent Application (PTO-900)
- 6) ☐ Other

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DETAILED ACTION

This Office action is in response to the communication filed October 25, 2001, Paper No. 13.

Claims 24-44 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Withdrawn Rejections

Rejection of claims 24-26 under 35 U.S.C. 102(b) as being anticipated by Evans et al is hereby withdrawn in light of Applicants' arguments filed October 25, 2001, Paper no. 13.

Rejection of claims 24-26 under 35 U.S.C. 102(b) as being anticipated by Sommergruber et al is hereby withdrawn in light of Applicants' arguments filed October 25, 2001, Paper no. 13.

Maintained Rejections

Claims 24-44 are rejected under 35 U.S.C. 112, first paragraph, for lacking adequate written description, for the reasons of record set forth in the Office action mailed April 24, 2001, Paper no. 10.

Applicant's arguments filed October 25, 2001 have been fully considered but they are not persuasive. Applicants argue that an adequate representation of the genus claimed has been provided in the instant application, which genus comprises oligonucleotides which bind to nucleic acids which encode any isoform of human tenascin and inhibit their expression. Contrary

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to Applicants' assertions, the specification discloses antisense oligonucleotides which specifically target and inhibit the expression of a single isoform of human tenascin. The disclosure of the successful targeting and inhibition of a single isoform of tenascin is not representative of the genus drawn to antisense oligonucleotides which specifically bind and inhibit the expression of any and/or all isoforms of tenascin. Therefore, the instant disclosure does not provide adequate written description for the genus claimed.

Claims 24-44 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement over the scope claimed, for the reasons of record set forth in the Office action mailed April 24, 2001, Paper no. 10.

Applicant's arguments filed October 25, 2001 have been fully considered but they are not persuasive. Applicants argue that ample evidence exists in both the antisense technology and gene therapy fields that such technologies are established tools. Contrary to Applicants' assertions, both antisense technology and gene therapy are still highly unpredictable in vivo, and in vitro results cannot be extrapolated to predict in vivo efficacy in achieving appropriate target cell delivery, target gene inhibition (or transfected gene expression), and further whereby treatment effects are provided. The instant disclosure is enabling for the scope drawn to the in vitro inhibition of expression of nucleic acids encoding human tenascin of SEQ ID NO: 1 by the antisense claimed. No in vivo data has been provided in the instant disclosure for the inhibition of this target gene (human tenascin of Seq ID NO: 1) in an appropriate animal model, nor have any treatment effects been provided in the instant application.

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Claims 24-35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denner et al, Cleek and Cleek et al in view of Baracchini et al and Friesen et al for the reasons of record set forth in the Office action mailed April 24, 2001, Paper no. 10.

Applicant's arguments filed October 25, 2001 have been fully considered but they are not persuasive. Applicants argue that the in vitro inhibition of human tenascin of SEQ ID NO: 1 would not have been obvious to one of ordinary skill in the art at the time the invention was made because the references of Denner and Cleek which were cited in the Office action mailed April 24, 2001, Paper No. 10, do not utilize antisense oligonucleotide comprising between 7 and 17 nucleotides. Contrary to Applicants' assertions, Denner and Cleek both teach antisense inhibition which target nucleic acids of SEQ ID NO: 1. Furthermore, the antisense oligonucleotides of the instant application merely comprise subsequences which have been previously disclosed by Denner for the inhibition of the target tenascin gene of the instant application. Claiming shorter oligonucleotides which are embedded within larger, previously disclosed oligonucleotides, (17 nucleotides compared to 18-22 nucleotide antisense oligonucleotides of Denner) does not render the instantly claimed antisense sequences non-obvious. Both the motivation and the means to inhibit the same target gene have been previously disclosed by others in the art, including Denner and Cleek. In addition, Applicants assert that since the antisense modifications previously disclosed by Baraccini et al and Friesen are not incorporated within antisense which target tenascin, it would not have been obvious to one of ordinary skill in the art to incorporate such modifications into the antisense of the instant

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application. Contrary to Applicants' assertions, it would have been a matter of routine experimentation to incorporate such modifications previously taught by Baraccini and Friesen into different antisense oligonucleotides. Such modifications have been successfully incorporated into an array of antisense oligonucleotides, targeting an array of target genes, and such modifications are not sequence dependent. Therefore the invention of the instant invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

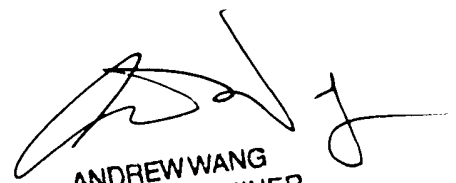
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Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

December 28, 2001


ANDREW WANG
PRIMARY EXAMINER